510(K) SUMMARY

Submitter's Name:	CoreLink, LLC
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Authorized Contact Name:	Meredith May, Authorized Contact Person
Contact's Telephone:	719-337-7579
Contact's Email:	MMay@EmpiricalTesting.com
Date Summary was Prepared:	12-Apr-13
Trade or Proprietary Name:	TIGER® Spine System
Common or Usual Name:	Orthosis, Spinal Pedicle Fixation Orthosis, Spondylolisthesis Spinal Fixation Orthosis , Spinal Interlaminal Fixation
Classification:	Class III per 21 CFR §888.3070 and §888.3050
Product Codes:	MNI, MNH, NKB, KWP
Classification Panel:	Orthopedic and Rehabilitation Devices Panel
Predicate Devices:	TIGER® Spine System (K110321, K120696, K113058, and K121728) Depuy Expedium Offset (K101070) Depuy Monarch (K024348 and K010576) EBI Omega 21 (K014137, K001357, K992333, K991721, K990303, and K973683) Medtronic Sofamor Danek TSRH-3D (K021170)

SEP 10 2013

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The TIGER® Spine System is a multiple component, posterior spinal fixation system which consists of pedicle screws, cannulated pedicle screws, posted pedicle screws, rods, cross-connectors, locking cap screws, hooks, and lateral offset connectors. All of the components are available in a variety of sizes to match more closely to the patient's anatomy. All components are made from titanium alloy described by such standards as ASTM F136.

CHANGE FROM PREDICATE:

The purpose of this submission is to make modifications/additions to the components of the TIGER® Spine System cleared in K110321, K120696, K113058, and K121728. The standard

construct is modified by the addition of hooks, cross-connectors, cannulated screws, and posted screws.

TECHNOLOGICAL CHARACTERISTICS:

The intended use and technological features of the modifications/additions to the components of the TIGER® Spine System do not substantially differ from the legally marketed predicate devices, which are the TIGER® Spine System (K110321, K120696, K113058, and K121728), Depuy Expedium Offset (K101070), Depuy Monarch (K024348 and K010576), EBI Omega 21 (K014137, K001357, K992333, K991721, K990303, and K973683), and Medtronic Sofamor Danek TSRH-3D (K021170). The predicate devices and the subject additions to the Tiger system are designed for posterior stabilization to provide immobilization and stabilization of spinal segments as an adjunct to fusion.

INDICATIONS FOR USE

The TIGER® Spine System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral spine (T1-S1/Ileum): degenerative disc disease (defined as discogenic back pain with degeneration of disc confirmed by history of and radiographic studies), degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis).

PERFORMANCE DATA

The TIGER® Posted Spine System constructs were tested in static axial compression, static torsion, and dynamic axial compression per ASTM F1717-11a. The TIGER® Spine System Hook constructs were tested in static axial and torsion grip per ASTM F1798-97. The TIGER® Spine System Cannulated Screw constructs were tested in static axial compression, static torsion, and dynamic axial compression per ASTM F1717-11a.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that TIGER® Spine System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

CoreLink, LLC
% Ms. Meredith May
Empirical Testing Corporation
4628 Northpark Drive
Colorado Springs, Colorado 80918

September 10, 2013

Re: K131250
Trade/Device Name: TIGER® Spine System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNI, MNH, KWP
Dated: July 18, 2013
Received: July 31, 2013

Dear Ms. May:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820): and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act): 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

Device Name: TIGER® Spine System

510(k) Number: K131250

The TIGER® Spine System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral spine (T1-S1/Ileum): degenerative disc disease (defined as discogenic back pain with degeneration of disc confirmed by history of and radiographic studies), degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis).

Prescription Use __X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Ronald P. Jean -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K131250